

REMARKS

Favorable reconsideration of this application in view of the remarks to follow is respectfully requested. Since the present amendment raises no new issues, and in any event, places the application in better condition for consideration on appeal, entry thereof is respectfully requested.

Before addressing the specific grounds of rejection raised in the present Office Action, applicants submit that Claims 1-9 are related to a cosmetic or pharmaceutical oil-in-water emulsion which comprises at least one polyether siloxane as recited in formula (I), having a proportion by weight of the polyether radical R of up to 45%, by weight, of the total mass. In accordance with the claims of the present application, the oil-in-water (O/W) emulsion is free of silicone oils. Claims 12, 13, 15 and 16 are directed to a process for preparing the claimed O/W emulsion, while Claims 17-23 are directed to an O/W emulsion that includes 10 weight percent or less of a monohydric alcohol and at least one polyether siloxane as recited in formula (I).

As indicated at Page 6, lines 1-5 of the present application, it was surprisingly discovered that by using hydrophobic polyether-modified polysiloxanes of formula (I) as an emulsifier component, it was possible to obtain homogeneous and stable O/W emulsions which contain little or no silicone compounds as oils components. In addition, and as indicated at Page 6, lines 5-10, it was surprisingly discovered that by using the claimed polyether siloxane, the consistency-imparting structures customary in cosmetic oil-in-water emulsions, be they the liquid-crystalline structures of the hydrophilic waxes or the gel structures formed from water-swallowable organopolymers, are less disturbed than using customary hydrophilic polyether siloxanes.

Claims 1-9 and 12, 13, and 15-23 stand rejected under 35 U.S.C § 103 as allegedly unpatentable over U.S. Patent No. 6,488,780 to Cauwet-Martin.

With respect to the obviousness rejection citing the disclosure of Cauwet-Martin, applicants submit that the claims of the present application are not obvious from Cauwet-Martin for the following reasons: Cauwet-Martin provides detergent and conditioning compositions having a washing base composed of surface active agents with a detergent powder and a conditioning system which is in the form of a nanoemulsion. In particular, the conditioning system is described at Col. 1, lines 54-56 as comprising at least one oil-in-water emulsion having oil globules with a mean particle size of less than 150 nm. Nanoemulsions are clearly differentiated from the emulsion, i.e., macroemulsion, appearing in the example at Col. 12, line 65-Col. 14, line 12.

In the prior example, the comparative composition, i.e., composition B, is an emulsion (i.e., a regular emulsion or macroemulsion) which has oil globules of approximately 1500 nm. See Col. 15, lines 57-58. This prior art example outlines that the use of nanoemulsions is *critical* for the stability of the detergent and conditioning composition. In particular, at Col. 13, lines 62-64, Cauwet-Martin states that “[T]he composition B is unstable and the oil separates out at the surface of the liquid, whereas the composition A is homogeneous and stable.” There are several important aspects to be considered: First, Cauwet-Martin discloses detergent and conditioning compositions which *comprise* an emulsion. The prior art reference does not teach emulsions as such. Secondly, Cauwet-Martin clearly discloses that the detergent and conditioning composition are only stable if they comprise a nanoemulsion as the conditioning component, irrespective of the type of emulsifier being used. Thirdly, it is observed that neither the nanoemulsion in the prior art example nor the emulsion of the prior art comparative example contain customary stabilizers.

The nanoemulsion of the prior art reference described in the example contains two organic emulsifiers (nonionic and ionic), avocado oil, ethanol, glycerin and water, and it is reported to have oil globules of approximately 60 nm. From the disclosure of Cauwet-Martin, it

is obvious that the way in which the emulsion is prepared (i.e., nanoemulsion vs. macroemulsion) is decisive for the achievement of a stable shampoo composition. Cauwet-Martin discloses that polyether siloxanes are preferred non-ionic amphiphilic lipids (see, Col. 5, lines 25-50), i.e., emulsifiers for the production of nanoemulsions, but not mandatory as can be seen in the given example. For the production of nanoemulsions, the prior art reference requires that a high-pressure homogenizer be used. See Col. 13, lines 36-37.

In contrast to the disclosure of Cauwet-Martin, the present invention provides emulsions, not detergent or conditioning compositions containing emulsions, prepared using a *conventional* procedure in which Phase A and Phase B were heated separately to 70°C, combined, and homogenized for 1 min. No special apparatus or conditions are provided for the homogenization process. See, for example, the preparation procedure mentioned in Example 8. The procedure used by the applicants in making their O/W emulsions is similar to that used in making the regular emulsion described as comparative in Cauwet-Martin except that in the claimed invention a polyether siloxane is specifically used while in the prior art example a polyether siloxane is not used. Hence, applicants' claimed invention is directed to regular emulsions, not nanoemulsions since no special apparatus or conditions are used for homogenization. If applicants intended to cover nanoemulsions, the application would not be enabling because no specifics were given on the homogenization procedure. Instead, conventional mixing is used in the present application; therefore a regular, i.e., macroemulsion, is being prepared.

Applicants' use of the term "emulsion" represents to one skilled in the art that the present invention is directed to macroemulsions, as is evident by the two articles contained in Exhibits 1 and 2 which were submitted to the U.S. Patent and Trademark Office on April 27, 2004. The unexpected finding of the present invention, which is described at Page 5, line 26-Page 6, line 20, may be summarized as follows: Only by using a selected and specific type of

polyether siloxane of formula I in combination with stabilizers known from the state of the art can one obtain homogeneous and stable (silicone oil-free) oil-in-water (macro)emulsions.

According to the teaching of Cauwet-Martin, on the other hand, (macro)emulsions using polyether siloxanes or any other type of emulsifier would provide a detergent and conditioning composition in which the oils phase separates out at the surface of liquid, whereas the composition containing nanoemulsions are homogeneous and stable. Hence, the disclosure of Cauwet-Martin teaches away from the claimed invention in which stable emulsions, not detergent or conditioning compositions comprising an emulsion, containing a specific polyether siloxane emulsifier can be obtained without the need of forming nanoemulsions. It is also observed that it is well known to those skilled in the art that the formation of a nanoemulsion by using, for example, a high pressure homogenizer, does not necessarily lead to a stable emulsion. It is the formula of the emulsion, in conjunction with the production process, that determiner whether the nanoemulsion is stable or not.

Moreover, one skilled in the art expects that the addition of stabilizers would lead to stable emulsions. It is, however, experienced that the addition of stabilizers is not sufficient to obtain homogeneous and stable (silicone oil-free) oil-in-water emulsions by using polyether siloxanes known in the art. See Example 9 of the present application. The teaching of the present application is that only a selected and specific type of polyether siloxane of formula I is compatible with commonly used stabilizers and that the claimed polyether siloxanes can be used to form homogeneous and stable emulsions (see Examples 8 and 9). The claimed polyether siloxanes are characterized as relatively hydrophobic amphiphiles, whereas classical oil-in-water emulsifiers are characterized as strongly hydrophilic ones.

The § 103 rejection also fails because there is no motivation in the applied reference which suggests modifying the disclosed compositions to include a regular emulsion, instead of a nanoemulsion. Thus, there is no motivation provided in the applied references, or otherwise of

record, to make the modification mentioned above. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Vaeck, 947 F.2d, 488, 493, 20 USPQ 2d. 1438, 1442 (Fed.Cir. 1991).

It is again emphasized that Cauwet-Martin not only teaches a different subject, namely a detergent or conditioning composition comprising a nanoemulsion instead of a regular emulsion as presently claimed, but also it teaches away from the claimed invention since in the prior art disclosure an example is provided in which the use of a emulsion (i.e., a regular emulsion or macroemulsion) which had oil globules of approximately 1500 nm did not work in stabilizing a detergent or conditioning composition. This comparative example provided in Cauwet-Martin indicates that the use of nanoemulsions is *critical* for the stability of the detergent and conditioning composition. Cauwet-Martin thus clearly teaches and suggests that stable compositions are only obtained in instances in which the emulsion is in the form of a nanoemulsion, irrespective of the type of emulsifier being used. Thus, the applied reference teaches away from using macroemulsions of the type presently claimed. Applicants submit that the applied reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. See, for example, Bausch & Lomb, Inc v. Barnes-Hind/Hydrocurve, Inc., 7967 F.2d, 443, 230 USPQ 416 (Fed.Cir. 1986). Applicants further opine that a reference is relevant for all it teaches to those skilled in that art. See, for example, In re Fritch, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992). Thus, since Cauwet-Martin discloses that macroemulsions can not be used to stabilize detergents and conditioning compositions, one skilled in the art would not consider to use such emulsions in or, even less, as cosmetic or pharmaceutical preparations.

In view of the above remarks, the rejection under 35 U.S.C. § 103 has been obviated. Applicants therefore request reconsideration and withdrawal of the instant §103 rejection.

In addition to the above general remarks, applicants take issue with several of the comments made in the Final Rejection. First, it was alleged at Page 3 of the Office Action, that Cauwet-Martin discloses stearic acid as an additional co-emulsifier. This is incorrect, Cauwet-Martin discloses at Col. 3, lines 5-7, that *salts* of stearic acid, not stearic acid, can be used as an anionic surfactant, and not as a stabilizer as presently claimed.

Applicants further submit that it was alleged in the present Office Action that the reference, i.e., Cauwet-Martin, is not anticipatory since it requires some “picking and choosing” to arrive at the claimed compositions and methods. Applicants respectfully submit that this statement made by the Examiner appears to support that the claimed invention is not obviousness from Cauwet-Martin since the applied reference does not recognize the critical of using the claimed polyether siloxane as an emulsifier which can provide a stable O/W emulsion. Instead, the principal reference generically mentions that silicone surfactants and esters of at least one poly can be used as the non-ionic amphiphilic lipid. See Col 5, lines 1-17. The example within the prior art does not use a silicone surfactant as the non-ionic amphiphilic lipid. Hence, it appears that one would first have to select a silicon surfactant as the non-ionic amphiphilic lipid, and then further choose a polyether siloxane of formula (I) and then, contrary to the teaching of Cauwet-Martin, provide an O/W emulsion that has oil globules of greater than 150 nm.

Applicants submit that the rejection appears to be a classical case of hindsight where one teaching has been selected from the prior art without considering the teaching of the applied reference as a whole. The applied reference teaches that stable compositions can be obtained only when a nanoemulsion is used, irrespective of the type of non-ionic amphiphilic lipid used. Cauwet-Martin provides no guidance to selectively choose a polyether siloxane having the formula recited in Claim 1 of the instant application and then use such a compound as emulsifier for making a stable O/W emulsion. Indeed, if one read the disclosure of Cauwet-Martin, one

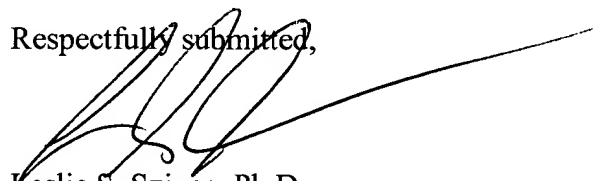
could use a polyether siloxane to make a nanoemulsion that can provide a homogeneous and stable composition. A quotation from the CCPA is particularly pertinent here:

The rejection here runs afoul of a basic mandate inherent in §103 –that “a piecemeal reconstruction of the prior art patents in the light of appellants’ disclosure” shall not be the basis for a holding of obviousness. In re Rothermel, 47 CCPA 866, 276, F. 2d 393, 396, 125 USPQ 328, 331 (1960). “It is impermissible within the framework of §103 to pick and chose from any one reference only so much of it as well support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art”. In re Wesslau, 53 CCPA 746, 750 353 F. 2d 238, 241, 147 USPQ 391, 393 (1965). We think this has been done here. In re Kamm, 172, USPQ 298, 301-02 (CCPA 1972).

Accordingly, applicants submit that the whole disclosure of Cauwet-Martin leads to providing nanoemulsions which, in turn, provide stable compositions. Cauwet-Martin does not teach or suggest however that by selecting the claimed polyether siloxane of formula (I) a homogeneous and stable regular emulsion can be obtained, especially not in the presence of customary emulsion stabilizers.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


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